AUG 1 0 2001

K010039

MEDgenesis

510 (k) SUMMARY

1. SUBMITTED BY:

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MEDgenesis, Inc.
6216 Bury Drive
Eden Prairie, MN 55346
952-974-4088 (phone)
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Summary prepared January 5, 2001

2. NAME OF DEVICES:

Trade Names:

QuickTek™ Blood Glucose System
QuickTek™ Blood Glucose Meter
QuickTek™ Blood Glucose Strips
QuickTek™ Control Solution

Common Names/Descriptions:

Blood glucose meter system

Classification Names:

Glucose test system, product code 75CGA, 21 CFR862.1345

3. PREDICATE DEVICE:

Duet Glucose Control Monitoring System
K973140 Duet L K990243

4. DEVICE DESCRIPTION:

Blood glucose monitoring system. The QuickTek Blood Glucose System consists of a meter, test strips, and control solution. It is intended for over-the-counter, home use by diabetics to monitor their blood glucose levels. The system tests capillary whole blood. The meter is a portable, battery-operated instrument designed for use with QuickTek Blood Glucose Strips. The blood glucose test strips may also be read visually against a color chart.

5. INTENDED USE:

QuickTek™ Blood Glucose System: Intended Use:
The QuickTek™ Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

QuickTek™ Blood Glucose Meter: Intended Use:

The QuickTek™ Blood Glucose Meter is intended for use with QuickTek™ Blood Glucose Strips for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

QuickTek™ Blood Glucose Strips: Intended Use:
QuickTek™ Blood Glucose Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood when used with the QuickTek™ Blood Glucose Meter or the manual color chart. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

QuickTek™ Control Solution: Intended Use:
QuickTek™ Control Solution is an aqueous glucose solution for use with the QuickTek™ Blood Glucose System. It is used as a quality control check to verify the accuracy of the blood glucose test result.

The QuickTek™ Control Solution is intended for use in the validation of the performance of the Blood Glucose System by providing a test solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The QuickTek system has the same technological characteristics as the predicate device.

7. NON-CLINICAL TESTING

Precision Study: Testing was performed using venous whole blood spiked to provide samples at five different glucose concentrations. The within-run precision tests consisted of twenty replicates of each of the five-spiked whole blood glucose levels. The within-run tests were performed in one day. The between-run precision tests consisted of twenty replicates per day at the five glucose concentrations for five additional days. The within-run and between-run precision values were substantially equivalent to that of the predicate.

Hematocrit Study: The hematocrit effect was evaluated at 30%, 40%, and 55% hematocrit levels. Testing was done using venous blood spiked with dextrose to provide samples at several different glucose concentrations. YSI plasma-referenced data was used for comparison. Results showed no significant hematocrit effect in the 30% - 55% range.

Altitude Study: Testing was conducted with both the QuickTek Normal and High Control Solutions. The study was performed at 900-foot and 10,660-foot elevations. All test

values fell within the appropriate control ranges and the mean values were nearly identical within each control solution, across the two altitudes. The QuickTek System is qualified at altitudes up to 10,000 ft. above sea level.

Dynamic Range/Linearity: Testing was conducted using whole capillary blood spiked with dextrose to provide samples to test the 20-600 mg/dL dynamic range. Testing was conducted using multiple lots of blood glucose strips, multiple QuickTek meters, and one YSI glucose analyzer. The results demonstrated linearity regression results substantially equivalent to those of the predicate, confirming the claim of a 20-600 mg/dL dynamic range.

8. CLINICAL TESTING

Accuracy/method correlation testing was done comparing the QuickTek System against the predicate and the YSI analyzer (reference method). Testing included both men and women, both Type 1 and Type 2 diabetes, ages from the twenties to eighties, and a wide range of educational levels. Tested blood glucose values encompassed the 30-90 mg/dL range on the low end to values over 250 mg/dL at the high end. Linear regressions statistics showed excellent correlation between QuickTek results and the YSI reference method, whether testing was done by the clinician or the patient. Regression statistics were substantially equivalent to those obtained for the predicate device.

9. CONCLUSIONS FROM TESTING

Testing demonstrated that performance of the QuickTek system was substantially equivalent to that of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 0 2001

Bruce A. MacFarlane, Ph.D.
Vice President of Regulatory Affairs and Quality Systems
Hypoguard USA, Inc.
5182 West 76th Street
Minneapolis, MN 55439

Re: 510(k) Number: K010039
Trade/Device Name: QuickTek™ Blood Glucose System, QuickTek™ Blood Glucose Meter, QuickTek™ Blood GlucoseStrips, QuickTek™ Control Solution
Regulation Number: 862.1345
Regulatory Class: II
Product Code: NBW
Dated: June 22, 2001
Received: June 26, 2001

Dear Dr MacFarlane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K010039

Device Name: QuickTek™ Blood Glucose System, QuickTek™ Blood Glucose Meter, QuickTek™ Blood Glucose Strips, QuickTek™ Control Solution

Indications For Use:

QuickTek™ Blood Glucose System: Intended Use:
The QuickTek™ Blood Glucose System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

QuickTek™ Blood Glucose Meter: Intended Use:
The QuickTek™ Blood Glucose Meter is intended for use with QuickTek™ Blood Glucose Strips for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

QuickTek™ Blood Glucose Strips: Intended Use:
QuickTek™ Blood Glucose Strips are intended for the quantitative measurement of glucose in fresh capillary whole blood when used with the QuickTek™ Blood Glucose Meter. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes as an aid to monitor the effectiveness of diabetes control.

QuickTek™ Control Solution: Intended Use:
QuickTek™ Control Solution is an aqueous glucose solution for use with the QuickTek™ Blood Glucose System. It is used as a quality control check to verify the accuracy of your blood glucose test result.

The QuickTek™ Control Solution is intended for use in the validation of the performance of the Blood Glucose System by providing a test solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Alexander for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010039

☒ OTC

(Optional Format 3-10-98)